other 4 patients developed either late AVB grade III (n= 3; day 9, day 14 and day 17 post TAVI) or progressive PR-interval lengthening in the presence of postinterventional LBBB (n=1; day 5 post TAVI).
Conclusion: Therefore late occurrence of bradyarrhythmias should be recognized as a significant contributor to postprocedural outcome after TAVI. Although this is a well known phenomenon after surgical valve replacement, it is less recognized after TAVI and should be considered in all patients after TAVI.

TCT-791

Transient increase in pressure gradient after TAVI – A question of dual antiplatelet therapy?

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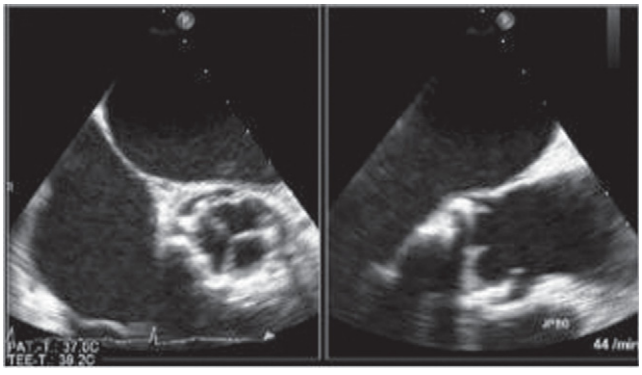
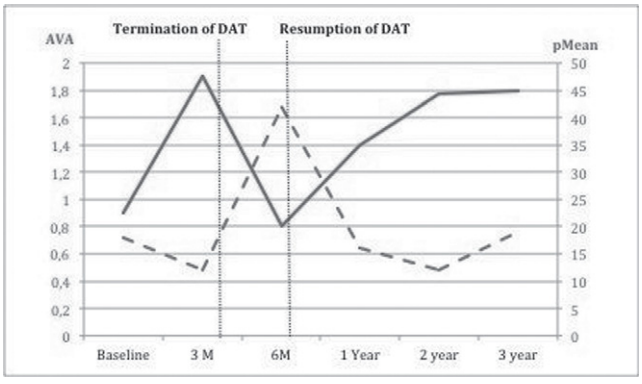
Background: Transcatheter aortic valve implantation (TAVI) has evolved to a viable tretment option for high-risk patients with severe aortic stenosis. While aspirine alone is considered adequate after bioprosthetic surgical aortic valve replacement, dual antiplatelet therapy (ASA & Clopidrogrel) is currently administrated for 6 months after TAVI to prevent thrombus formation. However, the need for dual-antplatelet therapy (DAT) and its duration is not supported by scientific evidence.
Methods: Since 2006 transfemoral TAVI was performed in 227 consecutive high-risk patients (Edwards n=139;Medtronic Corevalve n= 98). We report a case series of 4 patients who received an Edwards bioprosthesis and showed a transient increase in pressure gradients after termination of DAT.
Results: In one patient DAT was discontinued prematurely by the general practitioner at 3 months. This patient showed an increase of heart-failure symptoms (NYHA I-II → NYHA III) when he presented. This was accomplished by a significant increase of Pmean from 12 to 43 mmHg. Subsequent TEE (fig.1) revealed thickness of the leaflet tips with an impression of leaflet adhesion during opening. Resumption resulted in normalisation of pressure gradients (fig.2) and a normal valve function with unconspicious morphology. Similar findings were discovered in 3 additional cases.





Conclusion: A transient impairment of valve function was discovered in 4 TAVI patient after termination of DAT. This raises questions regarding the duration of this medical management and might potentially offer an explanation for the late strokes observed in cohort of the PARTNER trial, namely formation of microthrombi on the non-endothelialized surface of the bovine pericardial tissue leaflet.

TCT-792

A low-profile highly conformable sealing technology for transcatheter heart valves

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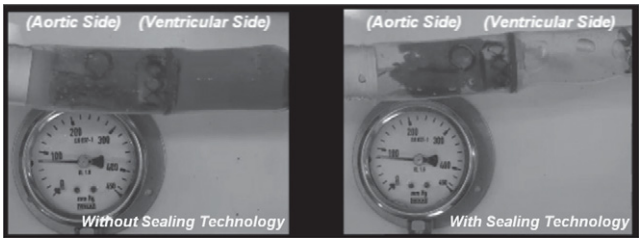
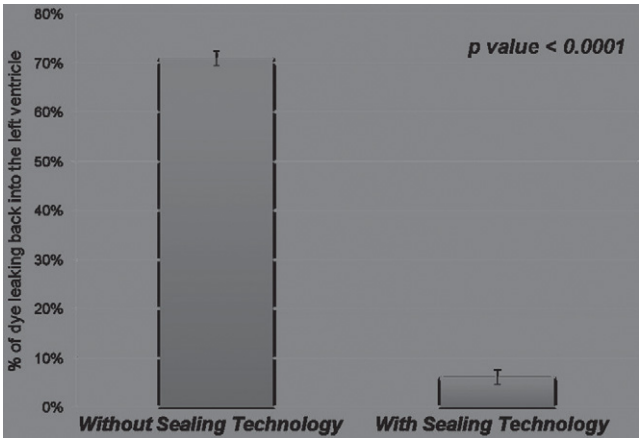
Background: Paravalvular aortic regurgitation (PVAR) frequently occurs after transcatheter aortic valve implantation (TAVI) and moderate to severe paravalvular incompetence is associated with poorer prognosis following TAVI. We have sought to develop a novel low-profile sealing system that is compatible with contemporary TAVI systems to eliminate PVAR.
Methods: A highly conformable TAVI sealing system has been developed and adapted onto prototypes of current ballon-expandable and self-expanding TAVI systems. The sealing system is activated without change in delivery steps for each system. The safety and efficacy of the sealing system has been assessed in vitro and in vivo.
Results: When adapted onto balloon-expandable and self-expanding TAVI systems, the sealing system did not increase device profile but produces a marginal increase in deployment force (approx. 2N). Sealing efficacy was assessed in hard polycarbonate models of aortic annuli modelled from patients who had suffered moderate or severe paravalvular regurgitation following TAVI. In a 100% of the cases, the PAVR was shown to be reduced to a none/trace level. Similar results were observed with the sealing mechanism even when TAVI devices were suboptimally positioned above or below the aortic annulus and also when placed in an oval-shaped annulus.



Snapshot of simulated aortogram comparing results for TAVI device implanted in a simulated hard calcified annulus with and without the sealing technology



Percentage of dye leaked back into the ventricle calculated as a function of the dye intensity

Conclusion: A low-profile, highly conformable sealing system can effectively seal paravalvular regurgitation when adapted onto contemporary TAVI systems. Utilization of specific seal technologies may effectively address paravalvular leaks following TAVI.

TCT-793

The Importance of Aortic Annular Area and Eccentricity on Balloon Expandable Aortic Valve Sizing, Geometry and Paravalvular Regurgitation

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Background: Sizing of a transcatheter heart valve (THV) is often determined by two-dimensional transesophageal echocardiographic (TEE) measurement of the aortic annulus. However the aortic annulus is typically oval and may be better evaluated by multi-detector computerised tomography (MDCT). The implications of an eccentric

POSTERS

aortic annulus with respect to sizing, expansion of the THV, and paravalvular regurgitation (PR) were evaluated.
Methods: Transcatheter aortic valve replacement (TAVR) of a SAPIEN XT THV was performed in 35 patients using standard TEE sizing criteria. The cross-sectional area and eccentricity of the aortic annulus and implant were determined from matched pre and post TAVR MDCTs. Eccentricity index (EI) was defined as 1-minimum diameter/maximum diameter of the pre-TAVR annulus or the post-TAVR THV. Expansion ratio (ER) was defined as THV area as determined by MDCT/nominal THV area. Nominal areas for the 23mm and 26mm balloon-expandable valves are 415mm2 and 531mm2 respectively. Implanted valves were deemed 'over-sized' when the nominal THV area was > the annular area and 'under-sized' when the nominal THV area was < the annular area. PR was assessed by TEE.
Results: Annular eccentricity was significantly reduced after TAVR (EI:22.5±7.1% vs.2.4±1.9%,p<0.001). An eccentric annulus did not correlate with expansion (r=0.08) or eccentricity of the implanted THV (r=-0.16). Valves were fully expanded in all cases (mean ER:105.2±5.6%). THVs were undersized in 34.5%(12/35). There was no difference in post-implant eccentricity or expansion whether the THV was over-sized or under-sized. (EI:3.2±2.7% vs.1.9±1.1%, p=0.15, ER :107.0±7.4% vs 104.2±4.4% p=0.23). The THV was undersized in 17.6% of patients with no/trace PR and 53.5% with mild PAR (p=0.04) and 66.6% with > moderate PR.
Conclusion: An eccentric annulus was not associated with eccentricity or under-expansion of balloon-expandable THVs. THV under-sizing, as assessed by MDCT annular area, was associated with increasing PR. Evaluation of the eccentric dimensions of the aortic annulus may improve THV sizing.

Valvular Heart Disease - Mitral

(Abstract nos 795 - 806)

TCT-795

MitraClip for Patients With Mitral Regurgitation Who are Ineligible for Surgical Repair or Replacement: A UK Based Cost-Utility Analysis

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Background: Treatment for individuals with symptomatic severe mitral regurgitation (SMR) involves a procedure to either repair or replace the mitral valve. However, a group of patients exist for whom such a procedure is deemed too high risk and who receive medical management (MM). Prognosis in this patient group is poor. MitraClip is a minimally invasive intervention for the treatment of SMR and as such may be of value in this patient group. The economic value of such innovative therapies should be assessed via the development of a cost-effectiveness model in the relevant patient group.
Methods: A ten year Markov model was developed in Microsoft Excel®. Treatment options included were MitraClip and MM. Mortality, adverse events and cross sectional NYHA data was taken from the EVEREST II High Risk Cohort and concurrent control group. The composition of MM was assumed to be the same as reported in a relevant UK health technology assessment and unit costs were taken from appropriate national databases. Decrements were applied to age-specific EQ-5D population norms to generate quality adjusted life years (QALYs). Extensive probabilistic and deterministic sensitivity analyses were undertaken. Costs and benefits were both discounted at 3.5% p.a.
Results: The base case incremental cost-effectiveness ratio (ICER) was £12,092 per QALY gained (95% CI £8,889 - £17,388) and £8,584 per life year gained. Treatment conferred an additional 3.63 years of life compared to MM. At a willingness to pay threshold of £20,000 per QALY gained, MitraClip had a 99.6% probability of being cost-effective. Results were not sensitive to changes in the method used to model baseline mortality, treatment related disutility, utility decrements, heart failure related hospitalisation rates and long term MitraClip related re-operation. The base case ICER is in line with those in other positive cardiovascular related appraisals undertaken by the UK National Institute for Health and Clinical Excellence (NICE)
Conclusion: MitraClip is a cost-effective treatment for patients with SMR who are currently ineligible for surgical repair or replacement.

TCT-796

EVEREST II High Surgical Risk Cohort: Clinical Benefit by MR Grade in High Surgical Risk Patients One Year Following MitraClip Therapy

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Background: Controversy remains on whether reduction of MR grade to 2+ is sufficient to provide improvements in clinical measures. This analysis will present measures of clinical benefit stratified by MR severity at 1 year in a large cohort of high surgical risk patients.
Methods: EVEREST II high surgical risk patients (n=211) with significant symptomatic MR with 1 year follow-up are included in this analysis. High surgical risk was protocol-defined as STS predicted or surgeon estimated operative mortality of ≥ 12%. Clinical benefit was measured by LV volumes, NYHA Class and Quality of Life scores and will be stratified based on MR severity at 1 year (≤ 1+ vs. 2+).
Results: A majority of high surgical risk patients had functional MR (71%), prior cardiac surgery (58%), and AF (64%). Mean predicted surgical mortality using the STS calculator was 12.2 ± 7.9%. Through 1 year, 50 patients died and 8 withdrew. Of the remaining patients with matched echocardiograms at baseline and 1 year (n=123), 82% achieved MR ≤ 2+ (36% with MR <=1+, n=44 and 46% with 2+ MR, n=57). Significant improvements in LV function, NYHA Class and QOL were observed with both 1+ and 2+ MR at 1 year (Table).

	Timepoint	LVEDV (ml)	LVESV (ml)	NYHA Class I/II (%)	Quality of Life PCS Score	Quality of Life MCS Score
MR ≤ 1+ at 1 year (n=44)	Baseline	155 ± 47 (n=41)	81 ± 40 (n=41)	2.3 (n=44)	32 ± 10 (n=34)	43 ± 14 (n=34)
	1 year	124 ± 38* (n=41)	63 ± 33* (n=41)	75.0* (n=44)	36 ± 10* (n=34)	48 ± 16* (n=34)
MR = 2+ at 1 year (n=57)	Baseline	165 ± 54 (n=53)	85 ± 45 (n=53)	21.1 (n=57)	35 ± 9 (n=48)	46 ± 14 (n=48)
	1 year	146 ± 50* # (n=53)	81 ± 41 # (n=53)	93.0* (n=57)	40 ± 12* (n=48)	54 ± 10* (n=48)

*p < 0.05 vs baseline, #p <0.05 vs MR=1+
PCS = Physical Component Summary, MCS = Mental Component Summary

Conclusion: MitraClip therapy significantly reduced LV size and improved NYHA Class and quality of life at 1 year regardless of residual MR (≤ 1+ vs 2+) in these high surgical risk patients. The MitraClip procedure is an important therapeutic option for select patients with significant MR at high risk of surgical mortality.

TCT-797

Immediate Mitral Valve Area After Successful Percutaneous Mitral Valvuloplasty: a Simple Predictor of Restenosis at Long-Term Follow Up

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Background: Objective: to investigate the factors associated with restenosis (RS) after successful percutaneous mitral valvuloplasty (PMV).
Methods: 132 patients (pts) who underwent PMV with Inoue balloon catheter were consecutively included. Successful results were defined as post-procedure mitral valve area (MVA) ≥ 1.5 cm2 as assessed by echocardiography and mitral regurgitation (MR) <3/4 grade (Sellers classification).Pts were clinical and echocardiographicaly evaluated immediately after procedure, 6 months after and once per year thereafter, evaluating Wilkins echocardiographic score (ES), mitral valve area (MVA), pulmonary artery systolic pressure (PAPs) and mitral regurgitation (MR). Following endpoints were considered: restenosis (RS), mitral valve replacement (MVR),new PMV requirement or death.A univariate and multivariate analysis were used to determine independent predictors for outcome. To assess the cut-off point of immediate post-PMV MVA for predicting restenosis 5 years after successful PMV, receiver-operating characteristic (ROC) curves were used; the optimal cut-off value was defined as the value with the maximal sum of sensitivity and specificity. A value of p <0.05 was considered significant.
Results: Median follow-up was 48 months (Q25-75: 24-84). The mean age was 44.2±13 years,115 pts were women. The median ES was 7; 28.3% of pts had ES> 8. There were 30.3% of pts with atrial fibrillation(AF).The median MVA before the procedure was 0.90 cm2; the PMV inmediate success was 78.8%.The median post-PMV MVA was 1.71 cm2. Long term outcomes are shown in table 1. The best immediate post-PMV MVA cut-off value for predicting RS was 1.8 cm2 (95%CI:1.5-1.9).There were 3 in-hospital deaths and 3 deaths at follow-up. ES>8(p=0.04) and postPMV MVA <1.8 cm2 (p =0.02) were associated with RS at 60 months follow-up.After multivariate analysis, the only variable associated with RS at follow up was post-PMV MVA < 1.8 cm2(OR:2.6,95%CI:6.2-1.1)

Table 1.

	12 months follow up	24 month	36 month	48 month	60 month
MVA (cm2)	1,61(1,3-1,9)	1,60(1,3-1,9)	1,59(1,4-1,9)	1,56(1,3- 1,8)	1,50 (1,34 a 1,86)
Restenosis (%)	20.7	27.4	25	28.2	29.4
PAPs (mmHg)median	33	32	31.5	32	32

Conclusion: Inmediate post-PMV MVA < 1.8 cm2 was an important predictor of restenosis and this value should be considered as a component of optimal result.

POSTERS